

Application Number 10/730,873
Amendment Responsive to Office Action mailed August 26, 2005

REMARKS

This Amendment is responsive to the Office Action dated August 26, 2005. Applicant has amended paragraph [0061] of the specification to correct a typographical error. Applicant has also: amended claims 1, 7, 12, 13, 15, 23, 30, 32, 38-40, 44, 47, 55, 56; 60 and 61; cancelled claims 52 and 57-59; and added a new claims 62-66. Claims 1-51, 53-56 and 60-66 are pending.

Drawing Objections

In the Office Action, the Examiner objected to the drawings under 37 C.F.R. § 1.83(a) as failing to show the "motion reduction element" recited in the claims. However, contrary to the Examiner's objection, the drawings do show examples of motion reduction elements. For example, FIG. 4A shows motion reduction elements 421.¹ As another example, FIG. 5B shows a motion reduction element 521.² Further, FIG. 7 shows motion reduction elements 722 and 723.³ Applicant respectfully requests that this objection to the drawings be withdrawn.

The Examiner also objected to the drawings as failing to comply with 37 C.F.R. § 1.84(p)(5) because they do not include reference sign 621, which was mentioned in paragraph [0061] of the specification. Applicant has amended paragraph [0061] to delete the mention of reference sign 621, which appeared in the specification due to typographical error. Applicant respectfully requests that this objection to the drawings be withdrawn.

Claim Objections

In the Office Action, the Examiner objected to claims 55 and 56 as including typographical errors. Applicant has amended claims 55 and 56 as suggested by the Examiner to correct the typographical errors, and therefore requests that the objections to claims 55 and 56 be withdrawn.

¹ See paragraphs [0047] and [0048] of the specification for accompanying text.

² See paragraphs [0055] of the specification for accompanying text.

³ See paragraphs [0062]-[0065] of the specification for accompanying text.

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Claim Rejections Under 35 U.S.C. §§ 102 and 103

In the Office Action, the Examiner rejected: claims 1-4, 9, 20, 21 and 56 under 35 U.S.C. § 102(b) as being anticipated by US 6,308,101 to Faltys et al. (Faltys); claim 6 under 35 U.S.C. § 103(a) as being unpatentable over Faltys; claims 5, 7-8, 10-19, 22-26, 30-43, 45-53 and 57-61 under 35 U.S.C. § 103(a) as being unpatentable over Faltys in view of US 6,176,879 to Reischl et al. (Reischl); claims 27 and 28 under 35 U.S.C. § 103(a) as being unpatentable over Faltys in view of US 6,358,281 to Berrang et al. (Berrang); claims 44 and 55 under 35 U.S.C. § 103(a) as being unpatentable over Faltys in view of Reischl and Berrang; and claim 29 under 35 U.S.C. § 103(a) as being unpatentable over Faltys view of US 2003/0073972 by Rosenman et al. (Rosenman). Applicant respectfully traverses these rejections to the extent such rejections may be considered applicable to the amended claims. The applied references fail to disclose or suggest the inventions defined by Applicant's claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

Claims 1-31

Independent claim 1

For example, the applied references fail to teach or suggest an implantable medical device comprising a plurality of interconnected modules, each of the modules comprising a respective one of plurality of housings, and an overmold that at least partially encapsulates each of the housings, as required by independent claim 1, as amended. The Examiner relied on Faltys as teaching both of these requirements of amended claim 1.

In general, Faltys discloses alternative embodiments for facilitating transmission of data and power between two modules of a cochlear implant system. One embodiment, referred to as the "wired system," includes a cable that connects the two modules for transmission of data and power between the modules.⁴ Another embodiment, referred to as the "proximity system," includes coils for inductive transfer of data and power between modules instead of a cable.⁵ More particularly, in the proximity system embodiments, one of the modules is electrically

⁴ Faltys: FIGS. 1D, 1F and 6; col. 2, ll. 51-55; col. 9, ll. 7-16; col. 14, ll. 1-9.

⁵ Faltys: FIGS. 1E, 3A and 3B; col. 3, ln. 62 – col. 4, ln. 17; col. 12, ll. 17-55.

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connected to an external coil, which may be encased in a silicone mold, and is positioned over a coil located inside of the other module.⁶

The Examiner cited the wired system embodiments of Faltys as teaching interconnected modules, as required by claim 1. The Examiner then cited the silicone mold from the proximity system embodiments as teaching an overmold, as required by claim 1. However, Faltys does not teach or suggest that a single device could include both the cable and the silicone mold and coil. Instead, Faltys teaches that these features are alternatives that perform the same function, and that either, but not both, may be included in a device.

For example, with respect to the proximity system embodiments, Faltys states:

There is no direct electrical or physical connection between the first and second devices through which power and/or control signals are communicated from one device to the other. That is, there is no detachable cable that connects the two devices together as is the case with the "wired system" embodiment. Rather, power and control signals are inductively (magnetically) coupled from the second device to the first device...⁷

Additionally, one of ordinary skill would have understood that inclusion of both a cable and a molded coil in a single device would have been redundant and therefore unnecessary, and therefore would not have been motivated to modify any of the devices taught by Faltys to include both features. Accordingly, Faltys does not teach or suggest an implantable medical device that includes both interconnected modules and an overmold, as required by independent claim 1.

Further, none of the other applied references provides any teaching or suggestion of a plurality of interconnected modules, each of the modules comprising a respective one of a plurality of housings, and an overmold that at least partially encapsulates each of the housings, as required by amended claim 1. In contrast, both Reischl and Berrang teach devices that include a single housing with two portions or sections, while Rosenman teaches catheter fixation helixes, and does not even discuss device housings.⁸ Accordingly, none of the other applied references provides any teaching or suggestions that would overcome the deficiencies of Faltys with respect to these requirements of amended claim 1.

As amended, independent claim 1 also requires that a portion of the implantable medical device is tapered to provide a sloped transition between an edge of the implantable medical

⁶ Faltys: FIGS. 3A and 3B; col. 12, ll. 32-41.

⁷ Faltys: col. 4, ll. 1-9.

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device and a surface of the patient, and an angle between the edge of the implantable medical device and the surface of the patient is greater than 90 degrees. The applied references also fail to teach or suggest this requirement of amended claim 1.

For example, contrary to this requirement, both Faltys and Berrang teach devices with rounded edges.⁹ Further, Faltys and Berrang do not even mention an angle between the edges of the devices and the surface of the patient on which they rest, i.e., the cranium. Nonetheless, the Figures in both Faltys and Berrang that depict the rounded edges of the device, appear to depict angles that are 90 degrees, i.e., perpendicular to the cranium, or less, contrary to the requirements of amended claim 1.

Like Faltys and Berrang, Reischl does not teach or suggest a device with a tapered portion, or discuss the angle between an edge of the device and the surface of the cranium on which it rests. Further, like Faltys and Berrang, the Figures of Reischl depict a device with rounded edges, and suggest an angle of 90 degree or less between the edge and the surface of the cranium.¹⁰ Nonetheless, the Examiner argued that Reischl "discloses an edge of first component 12 that provides a sloped interface with a surface of a patient 15 and an angle between the edge and the surface of the patient..."¹¹

Applicant respectfully disagrees. As illustrated in Figure 1 of Reischl, both of housing portions 12 and 13 provide parallel, rather than sloped, interfaces with the outer surface 15 of skull 16. Reischl teaches that placing a bend in the housing 11 of device 10 is advantageous because it results in parallel interfaces between portions 12 and 13 and outer surface 15.

Further, the Examiner argued that the angle recited in claim 1 is the unmarked angle supplementary to the marked angle in Figure 1 of Reischl, which Applicant has labeled θ in the modified reproduction of the Figure below.

⁸ Reischl: FIG. 1; col. 3, ll. 35-38. Berrang: FIG. 2, col. 9, ll. 39-40. Rosenman: Abstract.

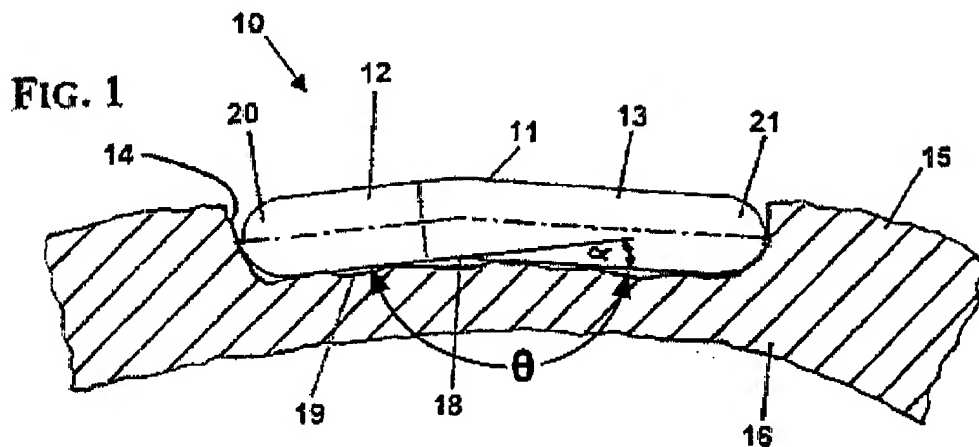
⁹ Faltys: FIGS. 3 and 4. Berrang: FIG. 2; col. 11, ll. 39-41.

¹⁰ Reischl: FIG. 1.

¹¹ The Examiner made this argument with respect to claims 12-17, 39-42 and 52 as previously presented, which included limitations similar to the identified limitation of amended claim 1.

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As can be seen in the Figure above, the angle α is an angle between a tangent from one bottom surface of the device 10 and the other bottom surface. The supplementary angle θ , cited by the Examiner, is an angle between the two bottom surfaces of device 10. In other words, the angle identified by the Examiner is not even an angle between a portion of the device and a surface of the patient, much less an angle between an edge of the device and the surface, as required by amended claim 1.

Additionally, even though Reischl does not even mention the angle θ , much less disclose or suggest a value or range for the angle, the Examiner argued that it would have been obvious make the angle fall within the range specified in claim 1. In support of this argument, the Examiner relied on holdings of Federal Circuit that discovering optimum ranges or values of result effective variables involves only routine skill in the art. However, "a particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation."¹² The holdings on which the Examiner relies are based on optimization of a value or range disclosed in the prior art that is different from the claimed range or value.¹³ Reischl does not even discuss the angle θ , much less disclose or suggest a value or range for the angle that one of ordinary skill could optimize. Accordingly, the holdings relied on by the Examiner are inapplicable to the present fact pattern.

¹² *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977); see also MPEP 2144.05.

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In sum, none of the applied references individually discloses or suggests that a portion of an implantable medical device is tapered to provide a sloped transition between an edge of the implantable medical device and a surface of the patient, and an angle between the edge of the implantable medical device and the surface of the patient is greater than 90 degrees, as required by amended claim 1. Accordingly, even if combined, the applied references would not render this requirement of amended claim 1 obvious.

Moreover, the Examiner did not cite any evidence of a motivation to combine the references, i.e., Faltys and Reischl. Instead, the Examiner merely discussed the features of Reischl that the Examiner argued constitute a disclosure of "an edge of first component 12 that provides a sloped interface with a surface of a patient 15 and an angle between the edge and the surface of the patient...." The Examiner did not discuss what modification would be made to the Faltys device based on the Reischl disclosure, how such a modification would result in a device meeting the requirements claim 1, or why one of ordinary skill would be motivated to make such a modification.

It is well established that the Examiner bears the burden of establishing a prima facie case of obviousness.¹⁴ In doing so, the Examiner must determine whether the prior art provides a "teaching or suggestion to one of ordinary skill in the art to make the changes that would produce" the claimed invention.¹⁵ A prima facie case of obviousness is established only when this burden is met. The Examiner has not met this burden with respect to the requirements of amended claim 1.

Claims 12-14

As amended, claim 12 further requires that an edge of the overmold is tapered to provide the sloped transition between the implantable medical device and the surface of the patient, and that an angle between the edge of the overmold and the surface of the patient is greater than 90 degrees. For at least the reasons stated above with reference to independent claim 1, the applied references fail to disclose or suggest these requirements of claims 12.

¹³ See MPEP 2144.05

¹⁴ *In re Oetiker*, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992).

¹⁵ *In re Chu*, 36 USPQ2d 1089, 1094 (Fed. Cir. 1995).

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Further, the mold 174 disclosed by Faltys is not tapered, and does not provide a sloped transition between the device described by Faltys the scalp of the patient, i.e., the surface of the patient that it would appear to contact as depicted in FIGS. 3A and 3B of Faltys. Nor is there any teaching in Faltys or the other applied references that would suggest tapering the mold 174 to provide such transition between the device and the scalp. The teachings in Reischl of a bent housing would have in no way suggested tapering the Faltys mold, which is separate from the Faltys housings.

Additionally, there is no teaching in Faltys or the other applied references that would have suggested modifying the mold 174 such that an angle between an edge of the mold and the scalp would be greater than 90 degrees, as required by claim 12, within a range from 120 to 150 degrees, as required by claim 13, or approximately equal to 135 degrees, as required by claim 14. As discussed above with reference to independent claim 1, the Examiner's reliance on holdings related to optimization of a value disclosed in the prior art to overcome the failure of the applied references to teach or suggest these requirements of claims 12-14 is misplaced. None of the applied references even mentions an angle relevant to the requirements of claims 12-14, much less a value for such an angle that could be optimized.

Claims 15-17

As amended, claim 15 requires a sloped interface element, separate from the overmold, that surrounds the overmold and provides the sloped transition between the implantable medical device and the surface of the patient, wherein an angle between an edge of the sloped interface element and the surface of the patient is greater than 90 degrees. Claim 16 requires that the angle is within a range from 120 to 150 degrees, while claim 17 requires that the angle is approximately equal to 135 degrees. For at least the reasons discussed above with reference to claims 1 and 12-14, the applied references fail to teach or suggest these requirements of claims 15-17. Moreover, nothing in the applied references would have suggested modification of the Faltys device to include a separate sloped interface element that surrounds the mold 174.

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Claim 5

As another example, the applied references fail to disclose or suggest an overmold that comprises a non-elastomeric material, as required by claim 5. The Examiner recognized that Faltys fails to disclose or suggest this requirement of claim 5. As recognized by the Examiner, Faltys teaches that mold 174, identified by the Examiner as corresponding to the overmold recited in Applicant's claims, is made from flexible silicone rubber.¹⁶ Nonetheless, the Examiner argued that Reischl discloses a non-elastomeric material, metal, and that it would have been obvious modify the mold 174 of Faltys to include the metal disclosed in Reischl "in order to reduce the mechanical stresses on the components housed within the device and on electrical connections." Applicant respectfully disagrees.

The metal disclosed in Reischl is a metal portion of a device housing itself.¹⁷ The teaching of a metal housing in Reischl would in no way have suggested modification of the mold 174 of Faltys, which is separate from the device housings described by Faltys, to include metal or a non-elastomeric material. Further, the supposed motivation cited by the Examiner, "to reduce the mechanical stresses on the components housed within the device and on electrical connections," would not have motivated any modification of the mold 174 described by Faltys. Including a metal or non-elastomeric material in the mold would not have reduced mechanical stresses on the components and electrical connections housed within the housings described by Faltys, because such housings are already rigid, and metallic or ceramic.¹⁸ Further, as discussed above, the housings described by Faltys are not electrically connected in embodiments that include the mold 174. Consequently, including a metal or non-elastomeric material in the mold would not have reduced mechanical stresses on electrical connections between the housings.

Additionally, this supposed motivation does not appear to have been found in the prior art. Applicant does not find this motivation in any of the cited references. Instead, the motivation appears to have been derived from Applicant's teachings related to intermodule motion reduction.

¹⁶ Faltys: col. 12, ll. 37-39.

¹⁷ Reischl: FIG. 1; col. 3, ll. 35-38.

¹⁸ Faltys: col. 12, ll. 17-34.

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Claims 7 and 8

As another example, the applied references fail to teach or suggest an overmold that comprises a first component that at least partially encapsulates each of the housings, and a second component that is positioned to surround at least one of the housings, as required by claim 7, as amended. Further, the applied references fail to teach or suggest that the first component is an elastomeric material, and the second component is a non-elastomeric material, as required by claim 8. None of the applied references even suggests an overmold that includes more than one component or more than one material, much less these requirements of claims 7 and 8.

For the same reasons advanced with respect to claim 5, the Examiner argued that it would have been obvious to modify the mold 174 of Faltys to meet the requirements of claims 7 and 8. However, the teaching of a metal housing in Reischl would not have motivated one of ordinary skill to make any modification to the mold 174 taught by Faltys, much less the modifications necessary to arrive at the requirements of claims 7 and 8. Further, as discussed above, the motivation for modification of the mold 174 cited by the Examiner would not have, in fact, motivated one of ordinary skill to make the modifications proposed by the Examiner, and appears to have been derived from the teachings of Applicant's specification.

Claim 10

As another example, none of the applied references teaches or suggests a lead connection module within the overmold for connecting an external lead to electronics within one of the plurality of interconnected modules, as required by claim 10. The Examiner recognized that the mold 174 described by Faltys does not include any lead connection module, but argued that it would have been obvious to include a lead connection module in the mold based on certain teachings of Reischl. However, the teachings in Reischl cited by the Examiner appear to have no relevance to the requirements of claim 10, and their application to the requirements of claim 10 is entirely confusing.

In particular, the Examiner appears to have argued that the teaching of an energy storage device and coil for inductive energy transfer within a housing, as described by Reischl, would lead to modification of the mold 174 of Faltys, which is external to the Faltys housings, to

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include a lead connection module for connecting an external lead. This argument is nonsensical. One of ordinary skill in the art would have recognized that the energy storage device and coil of Reischl are not an external lead connection module. Reischl does not suggest, nor would one of ordinary skill have ever envisioned, that the disclosed energy storage device and coil could be used to couple the disclosed therapy delivering lead 23 to other components of the Reischl device, as suggested by the Examiner. Further, the location of an energy storage device and coil within a housing, as taught by Reischl, would not have suggested locating an external lead connection module within an overmold that at least partially encapsulates a plurality of housings. There is no teaching in any of the cited references that would have suggested moving the connection for the cable 116 described by Faltys from the disclosed location to another location such that it would be within mold 174, much less any teaching that would have motivated one of ordinary skill to make such a significant modification to the Faltys device. The teachings of Reischl cited by the Examiner certainly would not have done so.

Claim 11

As another example, the applied references fail to teach or suggest a second overmold that at least partially encapsulates a lead connection module, wherein the second overmold is tethered to the first overmold, as required by claim 11. The Examiner's rejection of claim 11 is based on the rejection of claim 10, and is at least as confusing as that rejection. The Examiner appears to argue that it would have been obvious to one of ordinary skill to take the Faltys device as previously modified in view of Reischl, and further modify the device to meet the requirements of claim 11, because it has been held that "rearranging the parts of an invention involves only routine skill in the art." Applicant respectfully disagrees.

As discussed above, there is no teaching, suggestion or motivation in the applied references for modifying the Faltys device such that the connection for the cable 116 would be located within mold 174, as proposed by the Examiner with respect to claim 10. Additionally, further modification of the Faltys device such that it would include a second mold, again moving a connection of the cable so that is located within the second mold rather than the first mold, and having the first and second molds be tethered, are clearly not mere "rearrangement of parts," as suggested by the Examiner. Accordingly, the Examiner must identify some suggestion of and

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motivation for this significant further modification to Faltys within the prior art. The Examiner has not done so, and the applied references provide no such teaching or suggestion.

Further, the Examiner's statement that "it would have been obvious to...move the lead connection module from the first to the metal second component of the overmold" is confusing. Although it is not at all clear to Applicant, the Examiner appears to be referring to moving a lead connection module within the single housing described by Reischl to a different location within the housing.¹⁹ In any event, the modification proposed in this statement appears to be irrelevant both to the requirements of claim 11, and to modification of the Faltys device to meet those requirements.

Claims 23-25

As amended, claim 23 requires that the overmold includes an external lead management structure for external leads being routed away from the implantable medical device. Further, claim 24 requires that the overmold includes a groove to hold external lead material, while claim 25 requires that the overmold include a pouch to hold external lead material. The applied references fail to teach or suggest these requirements of claims 23-25. Faltys does not teach or suggest that mold 174 is located near or has any relationship with cable 116, much less includes any structure for managing the cable. Nor do any of the other applied references provide any teaching that would have suggested or motivated modification of the Faltys mold to include such a structure.

Nonetheless, the Examiner argued that the cover 25 on the housing 11 as taught by Reischl is, or includes, a lead management structure, pouch and groove as required by claims 23-25, and that these requirements are, therefore, obvious. This argument is not reasonable. The housing 11 disclosed by Reischl is not an overmold that at least partially encapsulates a plurality of housings. Nor is a cover that is separate from the housing equivalent to a pouch that is included as part of an overmold. Further, a feedthrough of the housing is not a groove included as part of an overmold.

Moreover, this argument is legally inadequate. This argument ignores the teachings of the primary reference, Faltys, and the necessity of modification of the device described by the

¹⁹ Reischl: FIG. 1; col. 3, ll. 35-38.

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primary reference in order to establish a prima facie case of obviousness. The Examiner may not simply point to a feature in a secondary reference and declare Applicant's dependent claims obvious. The Examiner must instead demonstrate that the teachings of the secondary reference would have suggested modification of the device of the primary reference to include the features required by the claims, and identify some teaching in the prior art that would have motivated one of ordinary skill in the art to undertake such modification of the device described by the primary reference.²⁰

In the instant case, the Faltys device already provides a header 115 that is associated with cable 116 and, as discussed above, cable 116 is not described as being in any way associated with mold 174.²¹ Accordingly, the teaching of cover 25 in Reischl would not have suggested or motivated any modification of the Faltys device, much less modification of mold 174 to provide a lead management structure, pouch, or groove for cable 116.

Claim 26

The applied references also fail to disclose or suggest an overmold that includes a removal assist structure for assisting the removal of the implantable medical device, as required by claim 26. The Examiner argued that the cover 25 disclosed by Reischl is a removal assist structure. However, the cover is not part of an overmold that at least partially encapsulates a plurality of housings, and Reischl does not even remotely suggest that the cover may be used for removal of the device described therein. Further, for the reasons discussed above, the mere citation of the cover in 25 in Reischl, the secondary reference, is legally insufficient for establishing a prima facie case of obviousness. The teaching of the cover in Reischl would not have motivated any modification of the device described by Faltys.

Claim 30

As another example, the applied references also fail to teach or suggest that the overmold includes a cap to cover a hole through the cranium, as required by claim 30, as amended. The Examiner argued that the housing 11 of Reischl covers a hole in the cranium. However, as

²⁰ *In re Chu*, 36 USPQ2d 1089, 1094 (Fed. Cir. 1995).

²¹ FIGS. 3A and 3B.

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discussed above, the single housing of the Reischl device is not an overmold that at least partially encapsulates a plurality of housings and does not, in any event, include a cap, as required by claim 30. Further, Reischl does not even mention a hole through the cranium, as required by claim 30 as amended. Additionally, as described above, the mere identification of a teaching in the secondary reference, Reischl, is not sufficient for a prima facie case of obviousness. The teachings of Reischl would not have suggested or motivated any relevant modification of the Faltys device.

For at least these reasons, the Examiner has failed to establish a prima facie case for non-patentability of Applicant's claims 1-32 under 35 U.S.C. §§ 102(b) and 103(a). Withdrawal of these rejections is requested.

Claims 32-46

Independent claim 32

As amended, independent claim 32 requires an overmold that includes a first component that comprises an elastomeric material at least partially encapsulates a housing, and a second component that comprises a non-elastomeric material and is positioned to surround the housing. None of the applied references even suggests an overmold that includes more than one component or more than one material, much less these requirements of amended claim 32. As discussed above with reference to claims 5, 7 and 8, the teaching of a metal housing in Reischl would not have motivated one of ordinary skill to make any modification to the mold 174 taught by Faltys, much less the modifications necessary to arrive at the requirements of claim 32. Further, as discussed above, the motivation for modification of the mold 174 cited by the Examiner would not have, in fact, motivated one of ordinary skill to make the modifications proposed by the Examiner, and appears to have been derived from the teachings of Applicant's specification.

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Claims 37 and 38

As other examples, none of the applied references teaches or suggests a lead connection module formed within the overmold for connecting an external lead to electronics within the housing, as required by claim 37, or that the second component of the overmold forms part of the lead connection module, as required by claim 38. For the reasons discussed above with reference to claims 10, 11 and 23-25, the rejections of claims 37 and 38 are confusing, inadequate, and in error.

Claims 39-42

Similar to claims 12-14, claims 39-42 require that an edge of the first component of the overmold is tapered to provide a sloped interface with a surface of a patient, and that an angle between the edge and the surface is greater than 90 degrees, within a range from 120 to 150 degrees, or approximately equal to 135 degrees, respectively. Similar to claim 15, claim 42 requires a sloped interface element that surrounds the overmold and provides a sloped interface with a surface of a patient, and that an angle between the edge and the surface of the patient is greater than 90 degrees. For the reasons discussed above with respect to claims 12-15, these requirements of claims 39 to 42 are not disclosed or suggested by the applied references.

Claim 46

Like independent claim 1, claim 46 requires a plurality of interconnected modules. For the reasons discussed above with reference to claim 1, the applied references fail to teach or suggest the requirements of claim 46.

For at least these reasons, the Examiner has failed to establish a prima facie case for non-patentability of Applicant's claims 33-46 under 35 U.S.C. §§ 102(b) and 103(a). Withdrawal of these rejections is requested.

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Claims 47-51 and 53-55

Similar to independent claim 1, independent claim 47, as amended, requires a plurality of interconnected modules, each of the modules comprising a respective one of a plurality of housings, and means for integrating the modules into a single structure that at least partially encapsulates each of the housings, wherein the means for integrating is tapered to provide a sloped transition between an edge of the means for integrating and a surface of a patient, and an angle between the edge and the surface is greater than 90 degrees. For the reasons discussed above with reference to claim 1, the applied references fail to disclose or suggest these requirements of amended claim 47. For at least this reason, the Examiner has failed to establish a prima facie case for non-patentability of Applicant's claims 47-51 and 53-55 under 35 U.S.C. §§ 102(b) and 103(a). Withdrawal of these rejections is requested.

Claims 56, 60 and 61

Similar to the requirements of independent claim 32, independent claim 56, as amended, requires a method comprising fabricating a non-elastomeric component to surround at least one of a plurality of housings, and fabricating an elastomeric component to at least partially encapsulate the housings and the non-elastomeric component. For the reasons discussed above with reference to independent claim 32, as well as claims 5, 7 and 8, the applied references fail to disclose or suggest these requirements of amended claim 56. For at least this reason, the Examiner has failed to establish a prima facie case for non-patentability of Applicant's claims 56, 60 and 61 under 35 U.S.C. §§ 102(b) and 103(a). Withdrawal of these rejections is requested.

New Claims:

Applicant has added claims 62-66 to the pending application. The applied references fail to disclose or suggest the inventions defined by Applicant's new claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention. For example, the references fail to disclose or suggest a sloped interface element that is separate from the overmold and surrounds the overmold, wherein the element comprises at least one of a flexible band, and o-ring, a removable flexible flange, or a tapered outer counter element, as

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required by claim 62. As another example, the applied references fail to teach or suggest an angle between an edge of an implantable medical device, first component of an overmold, sloped interface element, or integrating means on one hand, and a cranium on the other that is greater than 90 degrees, as required by new claims 63-66. No new matter has been added by the new claims.

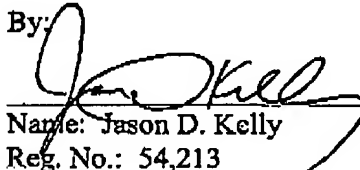
CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Date:

12-27-05
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